

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MOHAMMAD A. KHAN and DAVID P. HOPKINS

Appeal No. 1997-0926
Application No. 08/552,045¹

HEARD: September 13, 1999

Before COHEN, McQUADE and GONZALES, Administrative Patent Judges

GONZALES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 9, which are all of the claims

¹Application for patent filed November 2, 1995. According to appellants, this application is a continuation of application no. 08/294,213, filed August 22, 1994, now abandoned.

Appeal No. 1997-0926
Application No. 08/552,045

pending in this application.

We REVERSE.

Appellants' invention relates to a radiation compatible lubricant for a medical device such as an intravenous (IV) catheter. Claims 1, 4 and 7 are illustrative of the subject matter on appeal and are reproduced below:

1. A medical device coated with a mixture of a silicone based lubricant and either vitamin E or vitamin E acetate.

4. A method of sterilizing a medical device comprising: coating the medical device with a mixture of a silicone based lubricant and either vitamin E or vitamin E acetate; and irradiating the medical device.

7. A lubricant that does not substantially increase in viscosity after irradiation for use with a medical device, comprising a mixture of a silicone based lubricant and either vitamin E or vitamin E acetate.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Hyans 1984	4,459,318	Jul. 10,
Yoshida 1987	4,645,482	Feb. 24,
Wong et al. 1989 (Wong)	4,838,876	Jun. 13,
Valentine et al.	5,037,419	Aug. 6,

Appeal No. 1997-0926
Application No. 08/552,045

1991 (Valentine) Scarpelli et al. 1991 (Scarpelli) Soper 1991	5,043,161 5,071,706	Aug. 27, Dec. 10,
---------------------------------------------------------------------------------	----------------------------------------	--------------------------------------

The following rejections are before us for review:

(1) claims 1 through 3 stand rejected under 35 U.S.C. § 103 as being unpatentable over Yoshida in view of Valentine;

(2) claims 4 through 9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Yoshida in view of Valentine, as applied to claim 1, and further in view of Hyans;²

(3) claims 1 through 3 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wong in view of Soper and Scarpelli; and

(4) claims 4 through 9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wong in view of Soper and Scarpelli, as applied to claim 1, and further in view of Hyans.

² In that claim 7 is directed to a lubricant per se and is broader than claim 1, which is directed to the combination of a medical device coated with the lubricant, it is not clear why it was not included in Rejection (1).

Appeal No. 1997-0926
Application No. 08/552,045

The full text of the examiner's rejections and the responses to the arguments presented by appellants appear in the answer (Paper No. 15, mailed July 22, 1996), while the complete statement of appellants' arguments can be found in the brief (Paper No. 14, filed May 20, 1996).

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. Upon evaluation of all the evidence before us, it is our conclusion that the evidence adduced by the examiner is insufficient to establish a prima facie case of obviousness with respect to independent claims 1, 4 and 7. Accordingly, we will not sustain the examiner's rejections of claim 1, 4 and 7, and claims 2, 3, 5, 6, 8 and 9 dependent thereon, under 35 U.S.C. § 103. Our reasoning for this determination follows.

Appeal No. 1997-0926
Application No. 08/552,045

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Furthermore, the conclusion that the claimed subject matter is obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). The examiner may not, because of doubt that the

invention is patentable, resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis for the rejection. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Our reviewing court has repeatedly cautioned against employing hindsight by using the appellant's

Appeal No. 1997-0926
Application No. 08/552,045

disclosure as a blueprint to reconstruct the claimed invention from the isolated teachings of the prior art. See, e.g., Grain Processing Corp. v. American Maize-Products Co., 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988).

The Rejection of Claims 1-3 Under 35 U.S.C. § 103
Over Yoshida in view of Valentine

Claim 1 recites a medical device coated with a mixture of a silicone based lubricant and either vitamin E or vitamin E acetate.

Yoshida teaches a medical bag, such as a blood bag, comprising a pair of heat-sealable thermoplastic plastic sheets (e.g., polyvinyl chloride, polyolefin such as polyethylene, an ethylene-vinyl acetate copolymer or the like) (col. 4, lines 60-68) with polyvinyl chloride being the preferred material (col. 2, lines 12, 13). In order to prevent blood platelets from

adhering to the plastic sheets and the sheets from adhering to each other, the plastic sheets forming the sides of the bag are coated with a solution of a silicone resin composition containing dimethylsiloxane and an aminosilane coupling agent

(col. 1, lines 37-43 and col. 1, line 55 through col. 2, line 6). The resin solution reacts at room temperature with atmospheric moisture and is crosslinked to form gel-like layers on each of the sheets. The sheets are then superposed and heat-sealed around the peripheral portions of the sheets to provide a medical bag. Where the plastic sheets are made of polyvinyl chloride, the gel-like coatings also prevent elution of plasticizer from the sheets to the blood stored in the bag (col. 6, lines 58-60).

Valentine discloses that a suitable blood bag system can be made using vitamin E in combination with a flexible plastic material essentially free of blood extractables, such as plasticizers, found in conventional blood bags made of polyvinylchloride (PVC) (col. 1, lines 5-23 and 59-62).

According to Valentine,

[t]he vitamin E can be incorporated in concentrated form or added as solution in a suitable solvent, e.g. alcohol, at the desired concentration to the blood bag or at least one

compartment thereof. It is also contemplated that the vitamin E can be incorporated into the plastic material directly, using conventional techniques, so

that an effective amount of vitamin E will be in contact with the blood during storage.

It is believed that any method of incorporating the vitamin E into the blood bag system so as to increase the blood stability is suitable for the present invention. For example, the vitamin E can be present in the blood-containing compartment or can be stored in a second sealed compartment attached to the main body of the bag or the tubing and then added to the blood after blood collection. (Col. 7, lines 3-18).

The examiner describes Valentine as teaching "the coating of the inside of a blood bag with lubricous vitamin E" (answer, page 4) and concludes that "[i]t would have been obvious to one of ordinary skill in the art to add the vitamin E to the silicone resin of the inner layer of the blood bag of Yoshida to increase blood component stability" (id. at 4 and 5).

In our opinion, the examiner's stated position is based on impermissible hindsight gleaned from appellants' own disclosure and not from any fair teaching or suggestion found in the applied Yoshida and Valentine patents themselves. Contrary to the examiner's assertion, Valentine does not disclose that vitamin E

may be applied as a coating³ to the inside of the blood bag or that vitamin E is "lubricous" or useful as a lubricant. Rather, as correctly pointed out by appellants (brief, page 4), Valentine teaches the addition of vitamin E to increase blood component stability of blood stored in a blood bag that is essentially free of plasticizers. We can perceive no teaching in Valentine that the addition of vitamin E would have any beneficial effect on the stability of blood stored in a conventional PVC blood bag, which contains plasticizers, such as taught by Yoshida. Absent the disclosure of the present application, it is our opinion that one of ordinary skill in the art would not have been motivated to modify the blood bag of Yoshida in the manner urged by the examiner so as to arrive at the subject matter set forth in appellants' independent claim 1 on appeal.

For the reasons set forth above, the rejection of claim 1 under 35 U.S.C. § 103 based on Yoshida and Valentine is reversed.

³ Consistent with the specification, we construe the verb "coat" to mean "2. To cover with a layer, as of paint." Webster's II New Riverside University Dictionary, (1984).

Appeal No. 1997-0926
Application No. 08/552,045

Claims 2 and 3 are dependent on claim 1 and contain all of the limitations of that claim. Accordingly, the examiner's rejection of claims 2 and 3 will also be reversed.

The Rejection of Claims 4-9 Under 35 U.S.C. § 103
Over Yoshida in view of Valentine and Hyans

Claim 4 recites a method of sterilizing a medical device comprising the steps of coating the medical device with a mixture of a silicone based lubricant and either vitamin E or vitamin E acetate and irradiating the medical device. Claim 7 calls for a lubricant that does not substantially increase in viscosity after irradiation for use with a medical device, comprising a mixture of a silicone based lubricant and either vitamin E or vitamin E acetate.

The examiner cites Hyans as evidence that it was well known at the time appellants made their invention to sterilize medical equipment using radiation. It is the examiner's position that, in view of Hyans, "[i]t would have been obvious to one of ordinary skill in the art to sterilize the blood bag of Yoshida as modified by Valentine with radiation" (answer,

page 5).

Our review of Hyans reveals that it does not overcome the deficiency in the Yoshida-Valentine combination discussed above.

Thus, the rejection of claims 4 and 7 must also be reversed.

It

follows that the rejection of dependent claims 5, 6, 8 and 9 is likewise reversed.

The Rejection of Claims 1-3 Under 35 U.S.C. § 103
Over Wong in view of Soper and Scarpelli

The Wong patent is drawn to a silicone rubber catheter possessing improved surface morphology, at least the surface of the catheter to be inserted in the body having bonded thereto the reaction product of a composition comprising: (1) at least one crosslinkable polysiloxane; (2) an innocuous lubricating agent; and (3) a crosslinking agent (abstract). Wong defines "innocuous" to mean that the lubricating agent "will not

adversely react with the polysiloxane, e.g. preclude its ability to crosslink and thereby bond to the surface of the catheter" (col. 3, lines 7-10). The preferred lubricating agent is disclosed as silicone oil (col. 3, lines 17-20).

Both the Scarpelli and Soper patents are directed to the preparation of microencapsulated products having an oily core material. See, Scarpelli, col. 1, lines 6-16 and Soper, col. 1, lines 3-6. The products are disclosed as being useful in

emollients or deodorants. See, Scarpelli, col. 3, lines 28 and 29 and Soper, col. 3, lines 16-18. Among the materials described in each of the patents as being suitable for the core material are mineral oil, and other lubricant oils, emollients, fragrance oils, escalol and other oily sunscreen materials, aloe vera, silicone oil, jojoba oil, esters of vitamin E, such as vitamin E acetate, vitamin E linoleate, vitamin E palmitate, vitamin A, menthol eucalyptus formulations, fruit oils, e.g., lemon oil,

Appeal No. 1997-0926
Application No. 08/552,045

citrus base fragrance oil, and other citrus fragrances, oily color producing materials. See, Scarpelli, col. 2, lines 46-55 and Soper, col. 2, lines 36-45.

Having thoroughly reviewed the references relied on by the examiner, we find ourselves in agreement with appellants that neither Soper nor Scarpelli may be relied on as appropriate evidence of obviousness under 35 U.S.C. § 103. Appellants' invention relates to the field of medical devices and, more particularly, to lubricants for medical devices. Soper and Scarpelli are clearly not in the same field of endeavor as appellants' invention. Further, neither reference is reasonably pertinent to the particular problem with which the appellants

were concerned, i.e., lubricant degradation when exposed to radiation. Thus, we are of the view that both Soper and Scarpelli are nonanalogous art.

In addition, Wong teaches silicone oil as a lubricating oil in the disclosed composition because silicone oil will not

interfere with the ability of the polysiloxane component to crosslink. There is simply no teaching in either Soper or Scarpelli that vitamin E or vitamin E acetate has the same "innocuous" effect as silicone oil. Thus, absent the appellants' own disclosure, we can think of no reason why one of ordinary skill in this art would have been motivated to combine the diverse teachings of Wong and Soper or Scarpelli as the examiner has proposed. Accordingly, we will not sustain the examiner's rejection of claims 1 through 3.

The Rejection of Claims 4-9 Under 35 U.S.C. § 103
Over Wong in view of Soper, Scarpelli and Hyans

For the reasons set forth above, we will also not sustain the rejection of claims 4 through 9 under 35 U.S.C. § 103 based on Wong, Soper, Scarpelli and Hyans.

CONCLUSION

To summarize, all of the rejections of claims 1 through 9

Appeal No. 1997-0926
Application No. 08/552,045

under 35 U.S.C. § 103 are reversed.

REVERSED

IRWIN CHARLES COHEN)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
JOHN P. McQUADE)	APPEALS AND
Administrative Patent Judge)	INTERFERENCES
)	
)	
)	
JOHN F. GONZALES)	
Administrative Patent Judge)	

vsh

Appeal No. 1997-0926
Application No. 08/552,045

Richard J. Rodrick
Becton Dickerson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1880